REMARKS

Status of the Claims

Claims 1-7, and 9-14 are pending in the present application. Claim 8 has been previously canceled. No claim amendments currently have been made.

Rejections Under 35 USC 103(a) Over U.S. Patent No. 6,004,355 to Dias et al.

Claims 1-4, 6-7, 9-14 are rejected under 35 USC 103(a) as being obvious over U.S. Patent No. 6,004,355 to Dias et al. ("Dias"). The Examiner maintains this rejection for the reasons set forth in the previous Office Action of July 12, 2005.

In particular, the Examiner asserts that Dias teaches a hair coloring composition comprising an oxidizing agent, conditioning agents such as silicones, and sequestrant (chelant) agents of phosphonic acid derivatives and wherein the chelant is Glycinamide-N,N'-disuccinic acid which is a monoamine monoamide-N,N'-dipolyacid comprising more than one carboxylic acid group, wherein the composition has a pH of 10, wherein the composition further comprises methyl cellulose as a thickener and oxidative dye precursors, and wherein the composition is an aqueous solution. The Examiner also asserts that Dias teaches that the chelant is present in an amount of 0.5% [sic] to 2%. Additionally, the Examiner asserts that Dias teaches methods for coloring hair as well as a kit comprising an oxidizing agent and one or more coloring agents.

The Examiner acknowledges that the Applicants' claimed compositions differ from the teachings of Dias by reciting a composition comprising a chelant in an amount of greater than 2% to about 5%. However, the Examiner asserts that Dias broadly discloses compositions comprising a chelant in an amount of 0.05% to 20%, 0.01% to 10%, and 0.05% to 2%. Thus, the Examiner concludes that it would be obvious to one of skill in the art that to formulate the Applicants' claimed compositions by optimizing the level of chelant in the compositions disclosed in Dias in order to get the maximum effective amount in the hair dyeing composition. Applicants respectfully traverse the present rejection based on the following comments.

- A. A prima facie case of obviousness is not established because the level of chelant in a composition suitable for bleaching or dyeing hair is not recognized in the prior art as being a result-effective variable.
 - 1. Applicants' Argument

The Examiner has failed to establish a prima facie case of obviousness, and, thus, Applicants' claims are not obvious in view of Dias, because the level of chelant in a composition suitable for bleaching or dyeing hair is not recognized in the prior art as being a result-effective variable. Although "where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation," In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955), see also MPEP 2144.05, a particular parameter must first be recognized in the prior art as a result-effective variable before the determination of the optimum or workable ranges of such variable might be characterized as routine experimentation, see In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977), see also MPEP 2144.05.

As previously presented, Applicants' claim 1 recites a composition comprising an oxidizing agent, a conditioning agent selected from the claimed group, and a chelant, wherein the chelant is present at a level of greater than 2% to about 5% by weight of the composition, and wherein the composition has a pH from about 9.5 to about 11. Applicants' compositions, which contain chelants at a level in the claimed range, provide a good lightening effect to hair during oxidative treatments, such as bleaching and dyeing, which are carried out in the pH range claimed by Applicants, yet result in less damage to the hair than that which occurs during the use of known oxidative treatment compositions which contain chelants at levels of no more than 2%. It is believed that the chelants, when present at a level in Applicants' claimed range, act to chelate environmental and intrinsic heavy metal ions which would otherwise react with the oxidizing agent to give harmful species, such as free radicals, which damage the hair by oxidizing the disulfide bonds of hair. It is further believed that non-cationic conditioning agents such as silicones deposit less efficiently on damaged hair. Therefore, the chelants, by reducing oxidative hair damage, in turn, increase the efficiency of the deposition of the conditioning agents.

The prior art, however, does not recognize the level of chelant in a composition suitable for bleaching or dyeing hair to be result-effective with respect to preventing damage to the hair during oxidative treatments, and, in turn, increasing the deposition of conditioning agents on the hair. Notably, Dias characterizes chelants as an "optional component" of the hair coloring compositions of Dias. See Dias at column 23, line 63. A component which is just "optional" in a hair coloring composition cannot necessarily be

interpreted to be result-effective with respect to certain properties relating to the intended use of that composition. Further, Dias specifically teaches that "[s]uch sequestering agents [(i.e., chelants)] are valuable in hair coloring compositions as herein described for the delivery of controlled oxidising action as well as for the provision of good storage stability of the hair coloring products." Dias at column 24, lines 2-6. Dias mentions nothing about preventing damage to the hair through the use of certain levels of chelants.

For the purposes of controlled oxidizing action and good storage stability, which are recognized by Dias, chelants typically are included in hair coloring compositions at levels of 2% or less. Dias specifically teaches that chelants most preferably may be present in the hair coloring compositions from about 0.05% to about 2%. Moreover, every example composition in Dias comprises chelant at a level of 0.1%.

Although Dias broadly discloses that chelants may be present as an optional component at a level of about 0.005% to about 20%, Dias does not recognize the level of chelant to be result-effective with respect to reducing oxidative damage to hair during bleaching or dyeing treatments, and, in turn, increasing the deposition of conditioning agents on the hair. Consequently, as the prior art does not recognize the level of chelant in a composition suitable for bleaching or dyeing hair to be a result-effective variable, the determination of an optimum range within a broader range disclosed in the prior art cannot be considered to be routine experimentation. Therefore, the Examiner has failed to establish a *prima facie* case of obviousness.

2. Response to Examiner's Argument

Applicants previously presented the above argument in Applicants' Reply filed on January 12, 2006. In the Office Action of March 1, 2006, the Examiner asserts that such an argument is not persuasive. In particular, the Examiner disagrees with the above argument because Dias "teaches a composition comprising the sequestrant (chelant) agents and wherein the chelants are presented [sic] in the amounts of 0.05 to 10%, which covered [sic] the claimed range." Office Action of March 1, 2006, at page 2-3. The Examiner further asserts that "[t]herefore, there is sufficient motivation to one having ordinary skill in the art at the time the invention was make [sic] to formulate such a composition by optimizing the amount of the chelant agent in the composition in order to get the maximum effective amounts of these dyeing ingredients." Office Action of March 1, 2006, at page 3.

Applicants respectfully submit that the above argument presented by the Examiner is conclusory and fails to address Applicants' specific point that although Dias generally discloses a composition which may optionally comprise chelants in an amount of 0.05% to 10%, it would not be obvious to one of ordinary skill in the art to optimize the level of chelant to achieve Applicants' claimed compositions because only result-effective variables can be optimized and the prior art does not recognize the level of chelant in a composition suitable for bleaching or dyeing hair as being a result-effective variable.

The Examiner's argument in support of the present rejection is based on the assumption that formulating Applicants' claimed compositions is a matter of optimizing the chelant level within the broad range disclosed by Dias. However, according to *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977), and as described in MPEP 2144.05, only result-effective variables can be optimized. The Examiner has failed to make any assertion as to how or in what way the prior art recognizes the chelant level as a result-effective variable. Moreover, the Examiner has failed to refute the specific arguments made by Applicants as to why the chelant level should not be considered as being recognized in the prior art as a result-effective variable, such as chelants being only an optionally component in the compositions of Dias.

Consequently, the Examiner has failed to establish a prima facie case of obviousness, and Applicants' claimed compositions are novel and unobvious over Dias.

B Applicants' claims are not obvious in view of Dias because Applicants' claimed level of chelant is contrary to the accepted wisdom in the art.

1. Applicants' Argument

Alternatively, Applicants' claims are not obvious in view of Dias because Applicants' claimed level of chelant is contrary to the accepted wisdom in the art. The totality of the prior art must be considered, and proceeding contrary to accepted wisdom in the art is evidence of nonobviousness. See In re Hedges, 783 F.2d 1038, 1041, 228 USPQ 685 (Fed. Cir. 1986); see also MPEP 2145. The court in Hedges reversed the decision of the Board of Appeals and Patent Interferences, which had affirmed the examiner's rejection under 35 U.S.C. 103 of Hedges' claims. Hedges' claims were directed to a particular chemical reaction which occurred at a high temperature. In reaching its decision to reverse, the court noted that the references cited against Hedges' claims "all suggest that lower temperatures of reaction are preferable." Id. Thus, because

Hedges' claimed reaction temperature was contrary to the temperatures which were preferred in the art, the obviousness rejection was reversed.

As stated above, Applicants' claim 1 recites a composition comprising, inter alia, a chelant, wherein the chelant is present at a level of greater than 2% to about 5% by weight of the composition. In contrast, low levels of chelants, typically around 0.1%, are routinely used as stabilizers or preservatives in various oxidizing compositions for treating hair. Consistent with this general idea, Dias, while broadly discloses that chelants may be present as an optional component at a level of about 0.005% to about 20%, teaches that chelants most preferably may be present in the hair coloring compositions from about 0.05% to about 2%. Further, every example composition in Dias comprises chelant at a level of 0.1%.

Thus, similar to the claims at issue in *Hedges*, Applicants' claims are nonobvious over the prior art because they require a level chelant which is contrary to the accepted wisdom in the art.

2. Response to Examiner's Argument

Applicants previously presented the above argument in Applicants' Reply filed on January 12, 2006. In the Office Action of March 1, 2006, the Examiner fails to address or refute the above argument in any way.

Therefore, because proceeding contrary to accepted wisdom in the art is evidence of nonobviousness, as according to *In re Hedges*, 783 F.2d 1038, 1041, 228 USPQ 685 (Fed. Cir. 1986), and as described in MPEP 2145, Applicants' claimed compositions are novel and unobvious over Dias.

C. <u>Applicants' claims are not obvious in view of Dias because the Applicants'</u> claimed compositions possess superior and unexpected properties.

1. Applicants' Argument

Additionally, Applicants' claims are not obvious in view of Dias because the compositions of the present invention possess superior and unexpected properties versus compositions comprising a level of chelant which is both representative of the range of chelant level conventionally used in the art and within the most preferred range (i.e., 0.05% to 2%) disclosed by Dias. Although arguments of counsel cannot take the place of factually supported objective evidence, rebuttal evidence can be presented in the specification. See In re Soni, 54 F.3d 746, 750 (Fed. Cir. 1995). "Consistent with the

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Appl. No. 10/667,739 Atty. Docket No. CM2633MC Amdt. dated May 1, 2006 Reply to Office Action of March 1, 2006 Customer No. 27752

rule that all evidence of nonobviousness must be considered when assessing patentability, the PTO must consider comparative data in the specification in determining whether the claimed invention provides unexpected results." *In re Soni*, 54 F.3d at 750.

In the Deposition Test beginning at page 20, line 13 of the specification, Applicants have demonstrated superior and unexpected results with respect to the deposition on hair of a typical alkoxylated amine conditioning agent, PEG-2 soyamine, for a composition comprising 5% EDDS, which is representative of the claimed invention. The conditioning agent deposition results of this composition comprising 5% EDDS is contrasted with a composition comprising 1.2% EDDS, which is within the most preferred range of chelant disclosed in Dias, and with a composition comprising no chelant, which serves as a control.

First, for the composition comprising no chelant, the amount of PEG-2 soyamine deposited (as mg of PEG-2 soyamine deposited per gram of hair) was 0.02. Second, for the composition comprising 1.2% EDDS, the amount of PEG-2 soyamine deposited was 0.16. Third, for the composition comprising 5% EDDS, the amount of PEG-2 soyamine deposited was 0.51.

Thus, the composition comprising 5% EDDS provided the deposition of about 25.5 times more PEG-2 soyamine conditioning agent as the composition comprising no chelant. Further, the composition comprising 5% EDDS provided the deposition of about 3.2 times more PEG-2 soyamine conditioning agent as the composition comprising 1.2% EDDS.

Applicants respectfully submit that such conditioner deposition results for the composition comprising 5% EDDS, which is representative of the claimed invention, are clearly superior over the performance of the composition comprising 1.2% EDDS, which is within the most preferred range of chelant disclosed in Dias.

Applicants also respectfully submit that such results are commensurate with the scope of Applicants' claims. Interpolation between the deposition results for the composition comprising 1.2% EDDS and the composition comprising 5% EDDS suggests that deposition results for compositions comprising chelants at a level in Applicants' claimed range of greater than 2% to about 5% would be superior to compositions comprising chelants in the most preferred range disclosed in Dias.

2. Response to Examiner's Argument

Applicants previously presented the above argument in Applicants' Reply filed on January 12, 2006. In the Office Action of March 1, 2006, the Examiner asserts that the comparative data is not commensurate in scope with Applicants' claims. In particular, the Examiner asserts that Applicants' deposition test is specific in that it uses PEG-2 soyamine as a conditioning agent and EDDS as a chelant, whereas Applicants' claims are not limited to that specific type of conditioning agent and that specific type of chelant. Further, the Examiner asserts that Dias exemplifies EDTA as a chelant and not EDDS, which is the chelant used in Applicants' deposition test.

Applicants respectfully submit that the comparative data of the Deposition Test beginning at page 20, line 13 of the specification is sufficient to rebut a prima facie case of obviousness. "Office personnel should not require the applicant to show unexpected results over the entire range of properties possessed by a chemical compound or composition." See MPEP 2144.08, citing In re Chupp, 816 F.2d 643, 646, 2 USPQ2d 1437, 1439 (Fed. Cir. 1987). "[A]n exemplary showing may be sufficient to establish a reasonable correlation between the showing and the entire scope of the claim, when viewed by a skilled artisan." Id. More specifically, "a showing of unexpected results for a single member of a claimed subgenus, or a narrow portion of a claimed range would be sufficient to rebut a prima facie case of obviousness if a skilled artisan 'could ascertain a trend in the exemplified data that would allow him to reasonably extend the probative value thereof." See MPEP 2144.08, quoting In re Clemens, 622 F.2d 1029, 1036, 206 USPQ 289, 296 (CCPA 1980).

As described above, Applicants have demonstrated superior and unexpected results with respect to the deposition on hair of a typical alkoxylated amine conditioning agent, PEG-2 soyamine, for a first composition comprising 5% of the chelant EDDS. This first composition is representative of Applicants' claimed invention. The conditioning agent deposition results of this first composition is contrasted with a second composition comprising PEG-2 soyamine and 1.2% EDDS. This second composition is representative of a composition based on the disclosure of Dias. Dias teaches that its compositions may comprise chelants as an optionally component at a level most preferably within the range of 0.05% to 2%. And, although the exemplified compositions of Dias contain 0.1% of EDTA, Dias further discloses that EDDS is among those chelants suitable for use in its compositions. See Dias at column 24, lines 24-31. Therefore, this

second composition comprises a chelant disclosed in Dias and which is present at a level within the most preferred range taught by Dias.

As is further described above, the first composition comprising 5% EDDS provided the deposition of about 3.2 times more PEG-2 soyamine conditioning agent as the second composition comprising 1.2% EDDS. One of ordinary skill in the art could reasonably extend the probative value of this showing of superior and unexpected results for one member of the claimed genus (i.e., EDDS is an example of a chelant, as recited in Applicants' claims) to support the full scope of Applicants' claims based on the theory proffered by Applicants in the specification at page 3, lines 22-34.

Consequently, the comparative data presented by Applicants is sufficient to rebut a *prima facie* case of obviousness.

D. Conclusion

The Examiner has failed to establish a *prima facie* case of obviousness. Alternatively, Applicants' claims are not obvious in view of Dias because Applicants' claimed level of chelant is contrary to the accepted wisdom in the art. Moreover, Applicants have demonstrated superior results for the compositions of the present invention as currently claimed. Therefore, Applicants' claims 1-4, 6-7, and 9-14 are novel and nonobvious over Dias.

Rejection Under 35 USC 103(a) Over US Patent No. 6,004,355 to Dias et al. in view of US Patent No. 4,138,478 to Reese et al.

Claim 5 is rejected under 35 USC 103(a) as being unpatentable over US Patent No. 6,004,355 to Dias et al. ("Dias") in view of US Patent No. 4,138,478 to Reese et al. ("Reese"). The Examiner maintains this rejection for the reasons set forth in the previous Office Action of July 12, 2005.

In particular, the Examiner asserts that Dias teaches hair coloring compositions, as described above, wherein the compositions are thickened aqueous compositions. The Examiner acknowledges that Dias does not teach a hair treatment composition in the form of an oil-in-water emulsion. The Examiner then asserts that Reese teaches a hair bleaching or dyeing composition wherein the composition is in the form of a fluid bath, dry powder, paste, and cream emulsions of oil-in-water. The Examiner further asserts

that Reese also teaches hair color composition which comprises an oxidizing agent and a diphosphonic compound.

Thus, the Examiner concludes that it would have been obvious to one of skill in the art to formulate the composition of Dias in the form of an oil-in-water emulsion as taught by Reese because Reese describes different forms of hair treating compositions. Applicants respectfully traverse the present rejection based on the following comments.

The combination of Dias and Reese does not teach or suggest all of Applicants' claim limitations and, therefore, does not establish a prima facie case of obviousness. See MPEP 2143.03. Applicants' claim 5 contains the limitations of claim 1. As discussed above, Applicants' claim 1, as previously presented, recites a composition comprising, inter alia, a chelant, wherein the chelant is present at a level of greater than 2% to about 5% by weight of the composition. Applicants' compositions containing chelants at the claimed levels increase the deposition of conditioning agents on hair during or after an oxidative treatment, such as bleaching or dyeing, which is carried out in the pH range claimed by Applicants. This results in longer-lasting improved hair feel.

In contrast to Applicants' claimed compositions, both Dias and Reese fail to teach or suggest a composition comprising greater than 2 wt.% to about 5 wt.% of a chelant. As discussed above, even though Dias broadly discloses that chelants may be present as an optional component at a level of about 0.005% to about 20%, Dias indicates that the preferred chelant level is from about 0.05% to about 2%. Further, every example composition in Dias comprises a chelant at a level of only 0.1%. Likewise, while Reese broadly discloses that diphosphonic compounds may be used at a level of 0.01% to 10%, Reese teaches that the preferred level is 0.1% to 2%. As in Dias, the compositions of Examples 1, 2, and 3 of Reese comprise only 0.1% of a chelant.

Additionally, and most notably, after Reese states that the preferred level is 0.1% to 2%, Reese specifically teaches that "[l]arger amounts can be used if desired . . . but such larger amounts provide virtually no advantage" (emphasis added). See Reese at column 3, lines 19-26. Thus, despite the broad ranges disclosed in Dias and Reese, one of ordinary skill in the art would not be motivated to use a chelant at a level of greater than 2% in view of Reese's specific teaching against doing so.

Further, although Reese discloses that its compositions may be in the form of an emulsion, one of skill in the art would not be motivated to formulate the composition of

Date: May 1, 2006

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Dias into an emulsion because the peroxyacid oxidizing aids of Dias, which are required components of the compositions of Dias, are difficult to solubilize, especially in an oil-in-water emulsion.

The combination of Dias and Reese does not establish a *prima facie* case of obviousness for Applicants' claim 5. Accordingly, Applicants' claim 5 is novel and unobvious over the combination of Dias and Reese.

CONCLUSION

In light of the remarks presented herein, it is requested that the Examiner reconsider and withdraw the present rejections. Early and favorable action in the case is respectfully requested.

Applicant has made an earnest effort to place their application in proper form and to distinguish the invention as now claimed from the applied references. In view of the foregoing, Applicant respectfully requests reconsideration of this application and allowance of Claims 1-7 and 9-14.

Respectfully submitted,

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Signature

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